REMARKS

In the Office Action dated January 26, 2008, claims 1-7 were rejected under 35 U.S.C. §102(b) as being anticipated by Westenskow.

In response, a new method claim is submitted herein that replaces original method claim 1, and a new claim directed to an anesthesia system that replaces claim 7 are submitted herewith. Independent device claim 4 has been cancelled, and the claims previously depending therefrom now depend from new claim 10.

The method and anesthesia system disclosed and claimed in the present application are for the purpose of effectively removing carbon dioxide from gas that would otherwise be located in the dead volume or dead space of a breathing apparatus used to artificially respirate a patient, such as the anesthesia system. The term "dead space" or "dead volume" is well known to those of ordinary skill in the field of artificial ventilation of patients. In such an artificial ventilation system, as an unintended and undesired consequence of the arrangement of the components and conduits in the system, a location or volume may exist in which little or no flow of gas occurs, despite the active promotion of gas flow elsewhere in the system. Such a location is referred to as a "dead space" or "dead volume." As explained in the introductory portion of the present specification, frequently such a dead space is located at or near the Y-piece connector that forms the communication between the patient and the system. When the patient exhales carbon dioxide-containing gas, such gas proceeds into the dead volume and, as a result of little or no gas flow occurring within the dead volume, when the patient again inhales, the patient inhales this carbon dioxide-containing gas. Such systems conventionally contain a carbon dioxide absorber, which is intended to absorb carbon dioxide gas in the exhaled air

but, because the carbon dioxide-containing exhaled gas comes to be located in the dead space, it may not completely circulate, as intended, through the carbon dioxide absorber.

Moreover, in the case of anesthesia systems, a component known as a reflector is usually provided to adsorb and desorb the expensive anesthetic so that anesthetic exhaled by the patient can be returned to the gas flow that is supplied to the patient in the next inhalation in the respiratory cycle. The optimal location for placement of such a reflector is also at or near the Y-piece connector, and thus if that location happens to be a dead space in the particular anesthesia system in which the reflector is located, the reflector is also located in that dead space.

Evidence of the well known understanding of the term "dead space" by those of ordinary skill in the field of artificial ventilation, and in particular in the field of anesthesia equipment, is found in the text "understanding anesthesia equipment, 3rd Ed. (1994)." Copies of relevant pages 150-151 and 212-213 thereof are attached hereto as Exhibit A. The meaning of 'dead space" is explained at page 151 under the heading Mechanical (Apparatus) dead space." At page 213, the text describes the portion of a circle system that constitutes the breathing circuit dead space. As it so happens, the Westenskow et al reference is an example of such a circle system. At page 213, it is explicitly stated that the dead space "extends into the Y-piece as far as the partition." This of course applies to ventilators and anesthesia apparatuses equally.

This being the case, the Westenskow et al reference discloses nothing more than a standard circle system having a CO_2 absorber located in the circle path thereof. From the above definition of dead space, it is clear that the only dead space

in the Westenskow et al breathing circuit is the space within the common-line conduit between the patient and the partition Y-piece.

The basis of the present invention is to suction the expiration gases that would otherwise "stall" in the dead space between or during breadths by the patient, so that the CO_2-enriched expiration gas is not returned to the patient during the following inspiration phase. WO 91/19526 (corresponding to United States Patent No. 5,400, 778) describes another approach for reducing rebreathing of CO_2-enriched that inevitably collects in the dead space between successive expiration and inspiration cycles. Other examples of different methods addressing the same problem are described in United States Patent No. 6,761,166 and EP 1459778. A basic difference between these conventional approaches and the method and system disclosed and claimed in the present application is that, in accordance with the invention, the gas in the dead volume is filtered and *returned to* the dead volume or dead space, by virtue of being returned to the first gas flow path in which the dead volume is located. The method and system according to the invention thus provide an advantage that is not achieved in conventional approaches, namely that a consistent volume of gas is always supplied to the patient, because there is no need to compensate for "removed" gas, because all of the gas is returned to the flow path that contains the dead space.

The Westenskow et al apparatus does not address the problem of minimizing the CO_2 content of the gas within the machine dead space, and thus there is no disclosure, and no suggestion, in the Westenskow et al reference that describes the subject matter of new independent claims 9 and 10, nor provides any motivation to

modify the Westenskow et al reference to arrive at a method or system as set forth in claims 9 and 10.

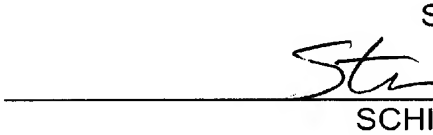
Although now cancelled, claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Perhag (The Reflector) in view of Westenskow et al. In the event that the Examiner may still consider the Perhag reference as being relevant to new claims 9 and 10, Applicant's comments concerning that reference are as follows:

The reflector disclosed in the Perhag reference does not constitute or represent a dead volume, since the gases passing through the reflector during expiration will have CO_2 filtered therefrom by the CO_2 absorber in the inspiratory branch of the system during inspiration. The heat-moisture exchanger (HNE) in the common-line conduit in Perhag does constitute a dead volume, but there is no teaching or suggestion in Perhag to provide a second flow path, in parallel with that dead volume, as set forth in each of claims 9 and 10. The Perhag reference, in this regard, thus does not provide any teachings beyond those of Westenskow et al. Modifying the Westenskow et al reference in accordance with the Perhag reference would merely result in a reflector being located in the dead space in the Westenskow et al system, but the aforementioned problems would not be overcome.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,



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UNDERSTANDING ANESTHESIA EQUIPMENT

Construction, Care and Complications

THIRD EDITION

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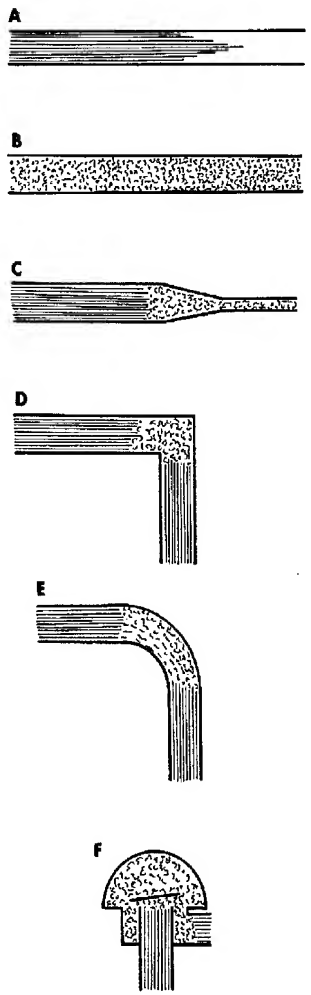


Figure 5.1. Laminar and turbulent flow. **A,** Laminar flow; the lines of flow are parallel and flow is slower near the sides of the tube, because of friction. **B,** Generalized turbulent flow, which occurs when the critical flow rate is exceeded. Eddies move across or opposite the general direction of flow. **C–F,** Localized turbulence, which occurs when there is change in direction or the gas passes through a constriction.

ance is directly proportional to flow rate with laminar flow.

Turbulent Flow

Figure 5.1*B* shows a turbulent flow of gas through a tube. The lines of flow are no longer parallel. Eddies, composed of fluid particles moving across or opposite the general direction of flow, are present. The flow rate is the same across the diameter of the tube.

For turbulent flow, the factors responsible for the pressure drop along the tube include those described for laminar flow, but also include gas density, which becomes more important than viscosity.

$$\Delta P = (L \times V^2 \times K)/r^5$$

where K is a constant, including such factors as gravity, friction, and gas density and viscosity. Resistance is proportional to the *square* of the flow rate with turbulent flow.

Turbulent flow can be generalized or localized.

Generalized Turbulent Flow. When the flow of gas through a tube exceeds a certain value, called the critical flow rate, generalized turbulent flow results.

Localized Turbulent Flow. As seen in Figure 5.1*C–F*, when gas flow is below the critical flow rate but encounters constrictions, curves, valves or other irregularities, an area of localized turbulence results. The increase in resistance will depend on the type and number of obstructions encountered.

Minimal apparatus resistance, therefore, dictates that gas-conducting pathways be of minimal length, maximal internal diameter, and without sharp bends or sudden variations in diameter.

Significance of Resistance

High resistance will place a burden on the spontaneously breathing patient. Changes in resistance tend to parallel changes in the work of breathing, which may be a more relevant parameter to study (2). Studies show that the tracheal tube is usually the source of more resistance and is a more important factor in determining the work of breathing than the breathing system (3). There is lack of agreement about what level of resistance is excessive (4,5). Anesthesia personnel should be aware of how much resistance components of breathing systems offer and to employ, wherever possible, those offering the least resistance.

For some patients, increased expiratory resistance may be desirable. It is suggested that this be achieved by using devices designed for this purpose.

REBREATHING

Rebreathing means to inhale previously respired gases from which carbon dioxide may or may not have been removed. There is a tendency to associate the word *rebreathing* with carbon dioxide accumulation. This is unfortunate because, although it is true that rebreathing can result in higher inspired carbon dioxide concentrations than normal, it is possible to have partial or total rebreathing without an increase in carbon dioxide. Total prevention of rebreathing is not always desirable.

Factors Influencing Rebreathing

The amount of rebreathing will depend on the fresh gas flow, the mechanical dead space, and the design of the breathing system.

Fresh Gas Flow

The amount of rebreathing varies inversely with the total fresh gas flow. If the volume of fresh gas supplied per minute is equal to or greater than the patient's minute volume, there will be no rebreathing, as long as provision is made for unimpeded expiration to atmosphere or a scavenging system at a point close to the patient's respiratory tract (5). If the total volume of gas supplied per minute is less than the minute volume, some exhaled gases must be rebreathed to make up the required volume (assuming no air dilution).

Mechanical (Apparatus) Dead Space

The mechanical dead space is the space in a breathing system occupied by gases that are rebreathed without any change in composition. The minimum volume of gas that can be rebreathed is equal to the volume of the mechanical dead space. An increase in dead space increases rebreathing. Apparatus dead space may be minimized by separating the inspiratory and expiratory gas streams as close to the patient as possible.

The mechanical dead space should be distinguished from the physiological dead space, which includes (*i*) anatomical dead space, consisting of the conducting airway of the patient down to the alveoli, and (*ii*) alveolar dead space, which is the volume of alveoli ventilated but not perfused.

The composition of gas in the mechanical dead space will vary according to whether it is occupied by anatomical dead space gas, alveolar gas or mixed expired gas. Gas exhaled from the anatomical dead space has a composition similar to inspired gas, but is saturated with water vapor and warmer. Alveolar gas is saturated with water vapor at body temperature and has less oxygen and more carbon dioxide than inspired gas. The concentration of anesthetic agent in alveolar gas will differ from that in the inspired gas. Mixed expired gas will have a composition intermediate between that of anatomical dead space and alveolar gas.

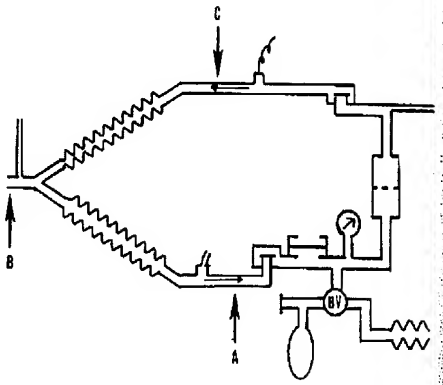
Design of the Breathing System

In addition to the above factors, the various components of a breathing system may be arranged so that there is more or less rebreathing. This will be discussed more fully under the individual systems.

Effects of Rebreathing

With no rebreathing, the composition of inspired gas is identical to that of the fresh gas

Figure 7.19. Possible locations for a spirometer (see text for details).



space may be significant. Use of this position may result in increased damage to the spirometer.

If the spirometer is placed on the inspiratory side (position C), during controlled or assisted ventilation it will overread volumes caused by expansion of the tubings and leaks between the spirometer and the patient.

Sensor for Airway Pressure Monitor

The sensor for an airway pressure monitor can be placed anywhere in the breathing system that the oxygen sensor can be placed (see Fig. 7.18). Most disposable systems do not allow placement at position F or G. Position B has the same disadvantages as placing the oxygen sensor at that point. To place the pressure sensor in the fresh gas line (position D) a special adaptor would be needed. In addition, the small diameter of the tubing and high flow of gas might result in falsely high pressures being sensed so that a low pressure in the breathing system might be missed.

Positions A, C, I, E, and H provide stable locations for the sensor. To use position I or H a special modification must be made to the dome of a unidirectional valve. T adaptors could be used in positions A, E, and C.

Positions on the expiratory side have an advantage over those on the inspiratory side. If there is obstruction to flow in the inspiratory limb and the sensor for airway pressures is located upstream of the obstruction, the low pressure at the patient will not be sensed. If the sensor is located downstream from the obstruction or on the expiratory side the low pressure will be detected.

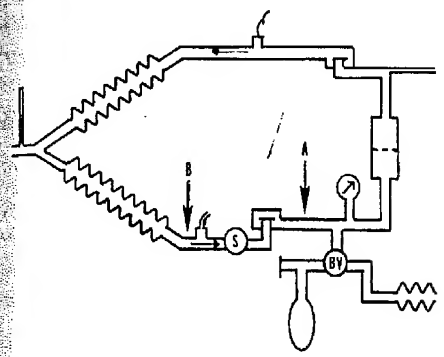
PEEP Valve

The positive end expiratory pressure valve must be placed in the expiratory side of the breathing system. A disposable PEEP valve should be placed between the expiratory breathing tube and the expiratory unidirectional valve (position B in Fig. 7.20). Built-in PEEP valves are usually situated downstream of the expiratory unidirectional valve and upstream of the absorber (position A in Fig. 7.20). A bidirectional PEEP valve may be inserted between the anesthesia ventilator and breathing system.

Pressure Manometer

To measure PEEP accurately, the pressure manometer must be on the same side (patient or absorber) of the expiratory unidirectional valve as the PEEP valve (90). On most older absorber assemblies the manometer is on the absorber side of the unidirectional valve. If a PEEP valve is added to the expiratory limb on the patient side of the unidirectional valve PEEP will not register on the manometer gauge. Most newer absorber assemblies have a built-in PEEP valve located on the absorber side of the unidirectional valve with the pressure manometer in close proximity.

Figure 7.20. Possible locations for a PEEP valve (see text for details).



Resistance and Work of Breathing in the Circle System

In the past, one of the objections to using a circle system with small children was that it had a high resistance. However, investigations have shown that the resistance or work of breathing with the circle system is not significantly greater than with other breathing systems and may be less in some cases (55,91–95).

There are no studies to indicate that there is any greater problem in letting an infant breathe spontaneously with a circle system as opposed to a nonrebreathing system (96).

Use of coaxial tubings increases resistance (55).

Dead Space of the Circle System

In the circle system, dead space extends into the Y piece as far as the partition. Use of a Y piece with a septum will decrease dead space. When exhalation or inhalation starts, the gases in the breathing tubes move in the opposite direction from their usual flow until stopped by closure of one of the unidirectional valves. This is referred to as *backlash* and causes a slight increase in dead space. If the unidirectional valves are competent, however, backlash will be clinically insignificant.

Heat and Humidity

In the circle system moisture is available from three sources: exhaled gases, the water content of the absorbent granules, and water liberated from the neutralization of carbon dioxide. Most inspired humidity is supplied by the absorbent; exhaled water vapor makes a small contribution (97). The amount derived from the neutralization of carbon dioxide is negligible.

Gases in the inspiratory limb of a circle system are near room temperature (98,99). Even with low fresh gas flows, gases reach the Y piece only 1° to 3°C above ambient temperature (100,101).

The humidity of a standard adult circle system using a fresh gas flow of 5 liters/min is shown in Figure 7.21. The initial inspired humidity was 30%. This rose to 61% in 90 min, stabilizing at this level. These values may be altered by the following factors.

1. Changing the fresh gas flow: Higher humidity results when lower fresh gas flows are used (81,100–103).